Remarks

Claims 1-10, 12-20, and 22-29 are pending. Claims 11 and 21 were previously canceled. Claims 1-10, 12-20, and 22-29 are rejected.

Objection under 37 U.S.C. § 1.75(c)

Claims 10 and 20 have been objected to under 37 CFR 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claims 10 and 20 have been amended. Applicant believes that the objection is moot in light of amendment to claims.

Rejections under 35 U.S.C. § 102(e)

Claims 1-10, 12-20, and 22-29 have been rejected under 35 U.S.C.§102(e) as being anticipated by Hossainy (US 6,926,919).

Claim 1 defines a method for fabricating a coating for an implantable medical device. The method comprises forming a first layer of the coating on the device and forming a water-soluble second layer of the coating on at least a portion of the first layer. The first layer includes at least one hydrophobic polymer and at least one hydrophilic polymer. The second layer includes at least one hydrophilic and amphiphilic polymer. The hydrophobic polymer and the hydrophilic polymer in the first layer have a mass ratio between about 49:1 and about 19:1. Therefore, claim 1 defines a coating having the first layer as an interior layer and the second layer as an outer layer on the top of the first layer.

Hossainy discloses a coating for an implantable medical device comprising a hydrophobic and a hydrophilic polymer (Column 2, lines 35-40). The mass ratio between

hydrophilic and hydrophobic polymers in the coating can be typically between about 1:100 and 1:9 (Column 3, lines 16-21). Thus, Hossainy describes a coating having a layer comprising a hydrophobic polymer and a hydrophilic polymer as the outermost layer, which corresponds to the second layer of the coating defined by claim 1 of the instant application which recites a hydrophobic polymer and an amphiphilic polymer. This coating therefore, has a configuration entirely different from the coating defined by claim 1. Therefore, Hossainy cannot anticipate claim 1 of the present invention. Accordingly, claim 1 is patentably allowable over Hossainy. Claims 2, 3, 4, 5, 6, 7, 8, 9 and 10 depend from claim 1 and are patentably allowable over Hossainy for at least the same reason.

Moreover, with respect to claim 8, the reference fails to teach the specific Hildebrand solubility parameter of between about 9.9 and about 10.1 $(cal/cm^3)^{1/2}$ for the amphiphilic polymers. Therefore, claim 8 is allowable not only based on its dependency from claim 1 but also because it teaches a different polymer and its solubility parameter.

Claim 12 is directed to a coating for an implantable medical device. The coating comprises forming a first layer on the device and forming a water-soluble second layer on at least a portion of the first layer. The first layer includes at least one hydrophobic polymer and at least one hydrophilic polymer. The second layer includes at least one hydrophilic and amphiphilic polymer. The hydrophobic polymer and the hydrophilic polymer in the first layer have a mass ratio between about 49:1 and about 19:1.

As discussed above, Hossainy describes a coating having an entirely different configuration from the coating of claim 12. **Hossainy fails to describe or teach forming a water-soluble second layer of coating having hydrophilic and amphiphilic polymers** as required by claim 12. Therefore, Hossainy cannot anticipate claim 12 of the

present invention. Accordingly, claim 12 is patentably allowable over Hossainy. Claims 13, 14, 15, 16, 17, 18, 19 and 20 depend from claim 12 and are patentably allowable over Hossainy for at least the same reason.

Moreover, with respect to claim 18, the reference fails to teach the specific Hildebrand solubility parameter of between about 9.9 and about 10.1 $(cal/cm^3)^{1/2}$ for the amphiphilic polymers. Therefore, claim 18 is allowable not only based on its dependency from claim 12 but also because it teaches a different polymer and its solubility parameter.

Claim 22 is directed to a method of surface modification of a coating on an implantable medical device. The method comprises (a) forming a first layer of the coating on the device, (b) forming a water-soluble second layer of the coating on at least a portion of the first layer and (c) **dissolving** the second layer in an aqueous medium to produce a coating layer having higher concentration of the first hydrophilic or amphiphilic polymer on the outer surface thereof than the average concentration of the first hydrophilic or amphiphilic polymer throughout the coating layer. The first layer includes at least one hydrophobic polymer and at least one hydrophilic or amphiphilic polymer. The second layer includes at least one hydrophilic or amphiphilic polymer. The hydrophobic polymer and the hydrophilic or amphiphilic polymer in the first layer have a mass ratio between about 49:1 and about 19:1.

Hossainy fails to describe forming a method that includes dissolving the outermost layer in an aqueous medium to produce a coating layer having higher concentration of the first hydrophilic or amphiphilic polymer on the outer surface thereof than the average concentration of the first hydrophilic or amphiphilic polymer throughout the coating layer as defined by claim 22. Further, **Hossainy deos**

not teach or describe specific concentration of hydrophilic or amphiphilic polymers as required by claim 22. Therefore, Hossainy cannot anticipate claim 22 of the present invention. Accordingly, claim 22 is patentably allowable over Hossainy. Claims 23, 24, 25, 26, 27, 28 and 29 depend from claim 22 and are patentably allowable over Hossainy for at least the same reason.

Moreover, with respect to claim 28, the reference fails to teach the specific Hildebrand solubility parameter of between about 9.9 and about 10.1 $(cal/cm^3)^{1/2}$ for the amphiphilic polymers. Therefore, claim 28 is allowable not only based on its dependency from claim 22 but also because it teaches a different polymer and its solubility parameter.

Withdrawal of the rejections and allowance of the claims is respectfully requested. Should the Examiner have any questions or concerns, the Examiner is invited to call the undersigned attorney/agent of record.

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